63. (amended) The method of Claim 61, wherein said cells exhibit [substantially] no specific hybridization to a Moloney-MLV retrovirus [*gag*, *pol*,] *gag-pol* or *env* probe[under stringent washing conditions].

REMARKS

Claims 1, 3-6, 8-11, 13-21, 36-38, and 42-70 are pending in the above-identified patent application and stand rejected. Claims 1, 3, 20, 46, 48, 50, 51, 53, 58 and 63 are amended.

Applicant's representatives thank the Examiner for the invaluable interview of January 31, 2002. The claims have been amended in accordance with the proposals that were discussed.

As set forth in the specification, for example, at page 6, lines 25-33, the invention is directed to non-primate mammalian cell lines that are useful for producing high titers of human serum-resistant retroviral particles (RVP). Underlying the invention is the observation that, in contrast to previous suggestions, the α-galactosyl moiety does not play a major role in determining whether the RVP or cell lines are resistant to human serum.

Previous studies suggested that the particular components of RVP responsible for serum sensitivity could be identified. For example, some investigators thought that α-galactosyl sugar moieties were the sole or major factor responsible for serum sensitivity and that serum resistant RVP could be produced by reducing or eliminating αGal from either producer cells from which the RVP were made, or from the RVP itself. In contrast, the Applicant shows that cells expressing αGal can be used to make RVP that are human serum-resistant even without treatment to remove αGal moities. In contrast to the prior art the Applicant shows that one seeking to produce human serum-resistant RVP should choose producer cells that are human serum-resistant.

As amended, Claim 1 now includes the proviso that the non-primate mammalian cell line is not BHK. As originally presented, Claim 1 was directed to preparation of a packaging cell line having no endogenous retroviral sequences that could be detected with a Moloney-MLV probe. The Examiner previously took the position that Claim

1 reads on BHK cells, which are disclosed by Rother, stating that there was no evidence in the art that BHK cells have endogenous Mo-MLV viruses.

Support for the proviso is found in the specification as a whole. The invention is directed to cell lines useful for producing high titers of human serum-resistant RVP. The specification shows that serum-resistant particles are produced by serum-resistant cells. In particular, disclosed cell lines such as Mpf and HT1080 are both human serum-resistant (Example 2, Fig. 1, Table 2) and capable of producing RVP that are human serum-resistant (Example 3, Fig. 2, Table 1). The specification also provides that the ovine MDOK cell line can be used, although it does not grow as well as Mpf cells (page 7, lines 16-18). Like Mpf and HT1080, MDOK cells are human serum-resistant. (Example 2, Fig. 1, Table 2). In contrast, the specification provides that BHK cells are not human serum-resistant (Example 2, Fig. 1, Table 2) and, accordingly, BHK cells are not within the invention.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 1, 3-6, 8-11, 13-21, 36-38 and 42-70 were rejected under 35 U.S.C. § 112, first paragraph as containing subject matter not described in the Specification in such a a way to reasonably convey that the inventor had possession of the claimed invention.

Claims 1, 48, 53, 58 and 63 were rejected for recitation of a Moloney-MLV *gag*, *pol* and/or *env* probe . . .". The clerical error has been corrected. Support is provided, for example, in Example 4 at page 28 of the Specification.

Claims 3 and 46 were rejected for reciting a cell line that expresses ". . . galactose α (1,3) galactosyl epitopes and is not treated to reduce such expression."

The disputed language has been deleted from the claims. As amended, the claims recite a non-primate mammalian cell line that is "human serum-resistant." Support is found, for example, in Example 2, starting at page 19 of the specification, which describes the analysis of human serum-resistance for seventeen cell lines and in Fig. 1, which depicts the results of the analysis.

It is believed that the rejections under 35 U.S.C. § 112, first paragraph are obviated by the claim amendments.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 1, 3-6, 8-11, 13-21, 36-38 and 42-45, 48, 53, 58 and 63 were rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of a cell or cell line that "exhibits substantially no hybridization . . . under stringent hybridization conditions."

As amended, the claims no longer contain the disputed language. The claims now recite a cell line that exhibits "no specific hybridization" to a Moloney-MLV retrovirus probe. Applicant asserts that the metes and bounds of the invention are made clear, for example, by the paragraph at page 7, lines 20-31, which provides that retrovirus probes should exhibit specific binding to any endogenous sequences that may be present. One of skill in the art would understand that specific binding means binding above background, and would know how to optimize hybridization conditions to distinguish specific binding.

Claim 20 has been amended to correct its dependencies.

Applicant believes that the claims are definite as amended, and respectfully requests that the rejection be withdrawn.

Conclusion

It is believed that the present application is in a condition for allowance which action is earnestly solicited. If the Examiner has any questions, he is invited to contact the undersigned.

Respectfully Submitted

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